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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,243

11/12/2003

Solomon S. Steiner

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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/706,243	<b>Applicant(s)</b> STEINER ET AL.	
	<b>Examiner</b> KONATA M. GEORGE	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16,19,20,22-27,31,32 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-26 and 40-49 is/are allowed.
- 6) ☒ Claim(s) 16,19,20,22,27,31,32,36-39 and 50-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 16, 19, 20, 22-27, 31, 32 and 36-53 are pending in this application.

#### ***Action Summary***

Any rejections of record that are not repeated below are considered withdrawn.

**The rejection of claims 16, 19, 20, 22, 27, 32, 37, 38, 39 and 50-53 under 35 U.S.C. 103(a) as being unpatentable over Debenedetti et al. or Sugaya et al. in view of Hunt et al. is maintained for the reasons stated in the office action dated January 28, 2008 and is repeated below.**

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 19, 20, 22, 27, 31, 32, 36-39 and 50-53 rejected under 35 U.S.C. 103(a) as being unpatentable over Debenedetti et al. (US 6,063,910) or Sugaya et al. (JP 363020301A) in view of Hunt et al. (US 4,866,051).

Applicant claims a microparticle having a size between 0.5 to 10 microns formed from a material releasing drug at a pH of 6.0 greater and wherein the material comprises alginate, chitosan and hydrophilic or hydrophobic proteins.

***Determination of the scope and content of the prior art***  
**(MPEP §2141.01)**

Debenedetti et al. teach in column 2, lines 24-15, 31-35 and 61-66, a method of forming protein microparticles, particularly hydrophobic protein microparticles (i.e. insulin, catalase, etc.) having a particle size of less than 10 microns. It is the position of the examiner that the recitation of protein includes all proteins, although it may be preferred that the protein is hydrophobic. Column 3, lines 17-40 teach that the particle can be made of a blend of materials in addition to the protein. These materials include the polymers cited in lines 36-40.

Sugaya et al. teach highly pure microparticles of chitosan having an average particle diameter of less than 10 microns (abstract) to be used as a carrier in the medical field.

***Ascertainment of the difference between the prior art and the claims***  
**(MPEP §2141.02)**

Debenedetti et al. or Sugaya et al. do not teach the microparticle releasing a drug at a pH of 6.0 or greater or that the particles are stored in a cartridge for insertion into a inhaler. It is for this that Hunt et al. is joined.

Column 3, lines 23-27 of Hunt et al. teaches the use of inhalation cartridges comprising particles having a size below 10 microns.

***Finding of prima facie obviousness***  
***Rational and Motivation (MPEP §2142-2143)***

The claim merely states that the microparticle is formed from a material that has that limitation, so any material that is claimed by applicant (i.e. proteins, amino acids, etc.) would have that limitation as well.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Debenedetti et al. or Sugaya et al. comprising dry particles in the invention of Hunt et al. comprising inhalation cartridges for particles. The expected result would be facilitating delivering the microparticle via inhalation.

***Response to Arguments***

Applicant's arguments filed May 27, 2008 have been fully considered but they are not persuasive.

Applicant argues that none of the three references teach or suggest a microparticle releasing the drug at a pH of 6.0 or greater. The examiner disagrees. The claims are drawn to a microparticle having a certain size (0.5 to 10 microns) comprising a drug and wherein the particles are formed of a material that releases the drug at a pH of 6.0 or greater. The material is selected from the group consisting of alginate, chitosan and hydrophilic or hydrophobic proteins. Looking at the claims, it is the understanding of the examiner that the material as claimed has the claimed release profile. Further understanding the claims the material is alginate or chitosan or hydrophilic or hydrophobic proteins. Looking at the particles of Debenedetti et al. and

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Sugaya et al. the material of the particles are hydrophobic proteins and chitson, respectively. Therefore, it is the position of the examiner that since Debenedetti et al. and Sugaya et al. teach the same material as claimed, the material would have the same inherent properties of releasing the drug at the claimed pH. The claim merely states that the microparticle is formed from a material that has that limitation, so any material that is claimed by applicant (i.e. lipids) would have that limitation as well.

It is also argued that the particles of Hunt et al. do not comprise an active agent and a polymeric material as claimed by applicant. The examiner agrees, however, Hunt et al. was not relied upon to teach the claimed particles. Hunt et al. was relied upon to teach a cartridge for insertion into inhaler can comprising particles having a particle size of 10 microns or less. Therefore, any type of particles whether they contain a polymer or not can be used in the cartridges of Hunt et al. as long as they had a particle size of 10 microns or less.

**The rejection of claims 23-26 and 40-49 under 35 U.S.C. 103(a) as being unpatentable over Cheatham et al. is hereby withdrawn in view of applicants' arguments.**

***Allowable Subject Matter***

Claims 23-26 and 40-49 are allowed. The prior art does not teach a method of delivering an active agent to the pulmonary system comprising microparticles which comprise diketopiperazine and an active agent, which have a diameter between 0.5 and

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10 microns and wherein the active agent is released from the microparticle at a pH of 6.0 or greater.

### ***Conclusion***

Claims 16, 19, 20, 22, 27, 31, 32, 36-39 and 50-53 rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Konata M. George/  
Primary Examiner, Art Unit 1616